ject, applicable to both single and multi-company projects. Any obligatory internal processes should be completed in tandem. **RESULTS:** Health outcomes studies, pharmacoeconomic evaluations, and risk sharing agreements for the access of new pharmaceuticals were identified as projects of high priority to implement in the following years. **CONCLUSIONS:** The steps outlined in this guidance, although not compulsory, will provide useful practical tips for how to go about setting up a Joint Working project in Catalonia (Spain), and to assist through the remainder of it. This guide is not a substitute for suitable regulatory or legal advice.

PHP201

MAPPING AND ANALYSING PHARMACEUTICAL POLICY SETTINGS WORLDWIDE

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OBJECTIVES: In the context of increasing demand and expenditure for health services it is important to elaborate policies which maximise efficiency. Pharmaceuticals account for about a fifth of total health care expenditure and are often target of health care efficiency policies. The aim of this study is to classify and grade pharmaceutical supply and demand control policies across the globe and cluster systems by regulatory rigidity. **METHODS:** Pharmaceutical policies and market data across 65 countries were researched in the literature with emphasis on pricing, reimbursement, dispensing, expenditure and demand control domains. Policies were classified by domains and graded through a multi-country expert survey for the degree of regulation. Cluster analysis helped to group countries by policy types. **RESULTS:** Pricing policies for on-patent products (with increasing degree of regulation) include: free pricing, direct negotiations, value-based-pricing, cost-plus-pricing, conditional-pricing, reference-pricing, state dictates and tenders. Cost control policies include: discounts, rebates, risk-sharing agreements, price-volume agreements, profit controls, pay-backs, claw-backs, margin cuts, price cuts, freezes, and tenders. Reimbursement policies include: variants of ATC5-based internal referencing, variants of statutory copayments, and variants of ATC4-based internal referencing. Dispensing policies were: no restrictions, indicative substitution, mandated or compulsory substitution. Demand controls include: educational campaigns, prescription aids, indicative prescription guidelines, indicative INN prescription, prescription monitoring, quotas, targets, predefined budgets, compulsory INN prescription, mandatory electronic prescription, compulsory prescription guidelines, prior/posterior approvals, sanctions and incentives for target/guidelines adherence. Cluster analysis identified a set of countries using an intermediate regulation policy approach and another with a more rigid approach. These did not differ significantly (p: 0.20) concerning pharmaceutical expenditure as % of GDP. **CONCLUSIONS:** A variety of policies were used in recent years for controlling pharmaceutical expenditures. Countries fall into two subsets based on the intensity of the regulation. More regulated systems do not appear to be associated with lower pharmaceutical expenditure.

PHP202

THE COST-EFFECTIVENESS OF PERIODIC SAFETY UPDATE REPORTS (PSURS) FOR BIOLOGICALS IN EUROPE

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OBJECTIVES: The safety profile of new drugs is usually not fully established upon market entry, giving cause for Europe's comprehensive pharmacovigilance system. A key regulatory vehicle to communicate the outcomes of pharmacovigilance activities is the Periodic Safety Update Report (PSUR), which summarizes a product's worldwide safety data and facilitates periodic assessment of its benefit-risk profile. We assessed the cost-effectiveness of all PSURs submitted in Europe during 1995-2009 for biologicals, using a societal perspective. **METHODS:** We evaluated two regulatory scenarios: Full Regulation (pharmacovigilance including PSURs) and Limited Regulation (pharmacovigilance without PSURs). We assessed the source of regulatory action for all urgent safety issues that were identified for biologicals during 1995-2009. In two out of 24 urgent safety issues (systemic spread of botulinum toxin and edema after use of dibotermin-alfa), PSURs were the regulatory instrument that identified the safety issue and we assumed these issues would have been discovered five years later under limited regulation. Estimates from the literature and Markov-chain life tables were used to calculate costs and effects of PSURs for biologicals. **RESULTS:** The incremental cost-effectiveness ratio (ICER) of Full Regulation versus Limited Regulation was €342,110 per quality-adjusted life year gained. Extensive sensitivity analyses indicated a low probability of the Full Regulation scenario being cost-effective. Only two parameters resulted in a more favorable ICER: a 100% risk reduction after identification of the urgent safety issues (base-case assumption was 25%) and a high risk (1 in 1,000 patients) of severe systemic spread after therapeutic use of botulinum toxin (base-case assumption 1 in 10,000 patients). **CONCLUSIONS:** Regulatory cost-effectiveness analysis is a feasible instrument for assessing the (added) value of parts of the drug regulatory framework. In light of high costs of regulatory compliance, cost-effectiveness should be a consideration in deciding whether or not safety-related regulatory actions are required.

PHP203

UTILIZATION OF THE HUNGARIAN PUBLICLY FINANCED HEALTH CARE SYSTEM BY THIRD (NON EU) COUNTRY CITIZENS

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OBJECTIVES: The number of citizens from third countries (outside of European Union or stateless) permanently living in Hungary is 205 000, and annually ca. 23000 people get permit to settle. Current study aims at exploring what group of foreigners, when and for what type of service use publicly financed health care. **METHODS:** Data was retrieved from National Health Insurance Fund Administration of Hungary (*NHIFA*) and Central Statistical Office. Current study's base was processing the last five years' statistical data (2007-2012), concerning health care of third country citizens permanently living in Hungary. We analyzed the volume, place and medical specialty of these services. **RESULTS:** In the last 5 years third country citizens required inpatient care 9414 times (61% in Budapest), emergency care 11776 times (63% in Budapest), out-patient care 72306 times (57% in Budapest). Patient accessed health care providers due to medical problems in the following medical fields: obstetrics (19%), surgery (18%), laboratory (18%), pediatrics (7%), and ophthalmology (6%). Most of the patients are from Ukraine (42 %), China (22 %), Vietnam (11 %), ex-Yugoslavia (6 %) and Russia (6 %). Analysis by nationalities shows that Chinese population requires health care relatively few times (for instance, 2011: 5%, in 2012: 6%) and even these are almost exclusively done in Budapest. In contrast USA citizens see doctors relatively often (2011: 8%, 2012: 8%), mainly in relation to diagnostics and curative surgery. From the neighboring non-EU states (23095 people, 31%) Ukrainian and (5709 people, 7%) ex-Yugoslavian citizens needed health care in the investigated period. Despite previous expectations, need for health care is not the characteristics of border regions but the capital city. **CONCLUSIONS:** Utilization of the Hungarian publicly financed health care system is significant by third country citizens. When planning health care capacity, this crucial fact must be taken into consideration.

PHP204

PHARMACEUTICAL REGULATION IN EUROPE AND ITS IMPACT ON CORPORATE R&D

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OBJECTIVES: Many European countries regulate drug prices in order to cope with rising health expenditures. On the other hand, price regulation distorts incentives to invest in pharmaceutical R&D. This study aims at empirically assessing the impact of price regulation on pharmaceutical R&D expenditures. **METHODS:** We analyze a sample of 20 leading pharmaceutical companies between 2000 and 2008. The share of sales in Europe serves as a proxy for the degree of price regulation. We control for other determinants of R&D such as cash flow, company size, leverage ratio, growth rate, and Tobin's q. **RESULTS:** Our results suggest a nonlinear relationship between European sales ratio and R&D intensity. Beyond a threshold of 33% of sales generated in Europe, a higher presence in Europe is associated with lower R&D investments. **CONCLUSIONS:** Price regulation has a negative impact on pharmaceutical R&D investments. Policy makers must take long term effects of regulation into account.

PHP205

ELICITING THE RELATIVE IMPORTANCE OF KEY ELEMENTS FOR BENEFIT-RISK ASSESSMENT: A COMPARISON AMONG GENERAL POPULATION, HEALTH AUTHORITY AND MEDICAL DOCTORS

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OBJECTIVES: This research was designed to find out the key attribute for benefit-risk assessment using swing weight method in general population, health authority and hospital doctors. **METHODS:** We selected six important elements for each benefit and risk assessment based on previous study. The elements of benefit assessment consisted of disease severity, size of population affected by disease, clinical guidelines recommendation, comparative interventions limitation, improvement of efficacy/effectiveness, improvement of quality of life. The attributes of risk assessment contained overall incidence of adverse events, overall incidence of serious adverse events, discontinuation rate due to adverse events, drug or food interactions, drugs of potential misuse, risk management. 583 subjects constituted 3 groups (general population, health authority and hospital doctors) were selected across the country by quota sampling method and performed survey to evaluate preference of each elements with the swing methods repeatedly. The trained interviewers assisted participant successfully completed survey. **RESULTS:** Improvement of efficacy/effectiveness and overall incidence of serious adverse events were revealed as the most important attributes than others for benefit- risk assessment in all three groups. Health authority group outweighed the improvement of efficacy/effectiveness [Mean (±SD): 0.208(±0.04)] and overall incidence of serious adverse events [Mean (±SD): 0.220(±0.05)], while 0.204(±0.03), 0.216(±0.04) in doctor group and 0.197(±0.04), 0.185(±0.04) in general population respectively. In six benefit attributes, the lowest preference score was clinical guidelines recommendation [0.114(±0.04)] in health authority group and [0.144(±0.04)] in general population while size of population affected by disease [0.126(±0.04)] in hospital doctor group. Among six risk elements, the lowest preference was drugs of potential misuse showed in health authority [0.117(±0.04)] and in hospital doctors [0.121(±0.04)] while risk management [0.121(±0.04)] in general population. **CONCLUSIONS:** This shows that improvement of efficacy/effectiveness among benefit attributes and overall incidence of serious adverse events among risk attributes are key elements for benefit-risk assessment.

HEALTH CARE USE & POLICY STUDIES – Risk Sharing/Performance-Based Agreements

PHP206

COVERAGE WITH EVIDENCE DEVELOPMENT IN SWEDEN – FORMALITY OR EFFECTIVE WAY TO REDUCE UNCERTAINTY?

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OBJECTIVES: TLV (formerly LFN) is responsible for reimbursement decisions in Sweden. They regularly give temporary reimbursement with request for additional